14. Individual and Groundwater Protection Requirements

14.1 INTRODUCTION

Both the individual and groundwater protection requirements of the disposal regulations -- 40 CFR part 191 subparts B and C -- apply to doses received from the wastes in the disposal system assuming that it is not disrupted by the occurrence of human intrusion or unlikely natural events. Specifically, the individual protection requirements at §191.15 limit the annual committed effective dose of radiation to any member of the public to no more than 15 millirem. The ground-water protection requirements §191.24 of subpart C, which limit releases to ground water to no more than the limits set by the MCL for radionuclides established in 40 CFR part 141. Both are concerned with human exposure to radionuclides from disposal systems and both limit such exposure for 10,000 years. Based on the similar forms of the two numerical requirements, EPA decided to adopt an approach that combines compliance criteria for these requirements into one section addressing the following issues:

- the definition of a protected individual,
- consideration of exposure pathways,
- consideration of underground sources of drinking water,
- the scope of compliance assessments, and
- the basis for a determination of compliance with these requirements (results of compliance assessments).

14.2 GROUNDWATER PROTECTION

The groundwater protection requirements of 40 CFR part 191 apply to USDWs in the accessible environment. Those USDWs that lie within the controlled area are not considered to be protected groundwater and the requirements of subpart C of 40 CFR part 191 do not apply. In 40 CFR part 194, the Agency implemented the requirements of subpart C of 40 CFR part 191 with the expectation that USDWs which lie closer to the disposal system will have a greater chance of being affected by releases of waste. In view of this, the analysis of the doses received from USDWs located large distances from the disposal system would not be likely to reveal information about the disposal system's performance not already disclosed by the analysis of those USDWs proximal to the disposal system. As a result, the groundwater protection requirements as implemented for the WIPP in §194.52 apply to those USDWs in the accessible environment that are expected to be affected by the disposal system over the regulatory time frame. The determination of which USDWs are expected to be affected shall be based upon the underground interconnections among bodies of surface water, ground water, and underground sources of drinking water.

Additionally, since the MCLs are applied equally to all USDWs, the "maximally exposed" aquifer will be determinative of compliance with the groundwater protection requirements. In other words, if the maximally exposed USDW is in compliance, then those lesser exposed USDWs, perhaps lying further from the disposal system, will likely be in compliance as well.

The Agency established the definition of the underground source of drinking water (USDW) in the promulgation of 40 CFR part 191 in 1993. The definition of USDW is taken directly from the Agency's underground injection control regulations found in 40 CFR parts 144 through 146. The complete description of the definition of USDW and the rationale which underpins it may be found in the Federal Register noticed which promulgated 40 CFR part 191, found at 58 Fed. Reg. 66398-66416.

In addition to considering interconnected USDWs, 40 CFR part 194 requires that the calculations of doses received from USDWs should assume that drinking water is withdrawn directly from the contaminated USDW and consumed at a rate of two liters per day. This requirement re-states the requirements of §141.16 of 40 CFR part 141. This latter regulation, which established the MCLs applicable to community water systems, stipulated that "dose equivalents shall be calculated on the basis of a 2 liter per day drinking water intake." This consistency between the two regulatory regimes reflects the Agency's desire to apply the underlying substantive requirements of the Safe Drinking Water Act to its program that regulates the disposal of spent nuclear fuel, high-level and transuranic radioactive wastes such as the WIPP.

In furtherance of this goal, the groundwater protection requirements of subpart C directly incorporate the maximum contaminant levels (MCLs) established under the Safe Drinking Water Act at 40 CFR part 141. Disposal systems shall therefore be designed to provide a reasonable expectation that 10,000 years of undisturbed performance after disposal shall not cause the levels of radioactivity in any USDW in the accessible environment to exceed the limits specified in 40 CFR part 141 as they exist on January, 19, 1994. Current SDWA MCLs for radionuclides were promulgated on July 9, 1976 (41 FR 28402) and became effective on June 24, 1977.

14.3 INDIVIDUAL PROTECTION

The requirements of §194.51 apply to the maximally exposed individual located in the accessible environment. The Agency designated the maximally exposed individual as the protected individual consistent with the stated objective of the disposal regulations. As noted in the promulgation of the disposal regulations in 1993:

> The EPA has chosen a 15-millirem CED [committed effective dose] per year limit because it finds the lifetime risk represented by this level of exposure to present an acceptable risk for the purposes of this rulemaking since it involves only a small number of potential sites and would result in only a small number of people potentially exposed to the maximum allowed individual risk.

Thus, to ensure that only a small number of persons will be potentially exposed to waste at the WIPP, the Agency required that, in compliance assessments of undisturbed performance, the protected individual must be the maximally exposed individual. Additionally, §191.15 of the disposal regulations specifies that "the disposal system shall not cause the committed effective dose, received through all potential pathways to the disposal system, to any member of the accessible environment to exceed 15 millirems." In the final rule for the WIPP, §194.52, therefore requires that the dose to individuals be calculated via all potential exposure pathways. In developing criteria for individual protection, the Agency reviewed the technical bases for release, transport, exposure, and dose and risk analyses supporting the promulgation of the disposal regulations. These analyses strongly suggested that the release and transport of radionuclides from a disposal system would most likely occur via ground water, and that the maximum radiation dose delivered to any individual beyond the site boundary would be the sum of the doses delivered through the water-dependent exposure pathways, e.g., consumption of contaminated drinking water, ingestion of products (i.e., meat and milk) from animals fed contaminated water, ingestion of crops irrigated with contaminated water, and direct radiation exposure due to radionuclides deposited on ground surfaces due to irrigation, among others. EPA also recognized that different dose and risks estimates were possible depending on the land use exposure scenario selected.

14.3.1 Consideration of Exposure Pathways (§194.52)

Given a plausible release scenario involving migration of contaminants from a disposal system via ground water to the accessible environment, several water-dependent exposure pathways are theoretically possible, including:

- ingestion of contaminated drinking water;
- ingestion of contaminated home-grown produce (fruits and vegetables) irrigated with contaminated well water;
- ingestion of meat (beef) from livestock fed contaminated well water or contaminated crops irrigated with contaminated well water;
- ingestion of contaminated milk from livestock fed contaminated well water or contaminated crops irrigated with contaminated well water;
- ingestion of contaminated soil irrigated with contaminated well water;
- dermal contact with contaminated soil irrigated with contaminated well water;
- inhalation of airborne suspended or resuspended contaminated soil irrigated with contaminated well water; and
- direct radiation exposure to photon-emitting radionuclides in soil irrigated with contaminated well water.

The maximum radiation dose delivered to the protected individual depends on several factors, including (but not limited to):

- all radionuclides and their range of concentrations in ground water;
- surface media that may become contaminated as a result of the potential ground water uses (e.g., drinking water, irrigation, dust suppression, etc.);
- exposure scenarios and pathways based on potential land uses (e.g., residential, commercial, industrial, agricultural, etc.); and
- exposure factor assumptions (e.g., intake rates, exposure times, etc.) and dose-to-risk conversion factors.

In order to implement an all-pathways analysis of the radiation dose that a member of the public receives it is necessary to decide: (1) where the person is to be located; (2) the human intake, radiation risks, and dose calculations to be used; and (3) the environmental pathways to be considered, the appropriate scenarios, and pathway parameter values to be used.

14.3.2 Location of Protected Individual

§191.15 limits the annual dose from the waste in the disposal system to any member of the public in the accessible environment. The definition of the accessible environment includes the ground surface on the WIPP Site. However, the preamble to the Final 40 CFR part 191 Rule says that "Groundwater withdrawn for consumption directly from within the controlled area need not be included in the analyses because geologic media within the controlled area are an integral part of the disposal system's capability to provide long-term isolation" (58 FR 66403).

14.3.3 Calculation of Radiation Dose

Appendix B of 40 CFR part 191 describes how the Annual Committed Effective Dose is calculated once individual organ doses in rads are obtained. Consistent with the future states assumptions, the radiation weighting factors and the tissue weighting factors are assumed to remain unchanged in the future. The dose calculations also require concentrations of individual radionuclides present in the air, water, and foods taken into the body and the applicable rates of air, water, and food intakes. Then, dose conversion factors are necessary to relate the intake of a radionuclide to the Committed Effective Dose.

14.3.4 EPA's Standardized Exposure Scenarios and Default Exposure Parameter Values for Human Health Risk Assignment

One example of the treatment of exposure scenarios is that used by EPA's Superfund program and Office of Radiation and Indoor Air (ORIA) to assess human health risks to individuals due to exposure to hazardous chemical substances and radionuclides from cleanup sites. These exposure scenarios provide an example of an approach that uses all-pathways of exposure to a maximally exposed individual. The specific application of the final rule, 40 CFR part 194, will depend on the specific considerations of the WIPP site and the surrounding region. These EPA guidelines assume reasonable maximum exposure (RME) conditions under different post-cleanup cases including the following four land-use classifications: 1) residential, 2) commercial/industrial, 3) agricultural, and 4) recreational. This section defines, for each scenario, the principal exposure pathways, key exposure parameters, and standardized default parameter values. Several EPA documents may be consulted for additional information (see references: EPA89a, EPA89b, EPA91a, EPA92, and EPA94). For additional illustration, Table 14-1 compares EPA, DOE, and NRC intake rates and exposure assumptions that could be used as default values in the scenarios.

EPA's Superfund program currently defines exposure scenarios within the context of the four land-use classifications listed above (EPA89a and EPA91a). EPA defines RME as "the maximum exposure that [any individual] is reasonably expected to [receive] at a site" (EPA89a) or as the "high-end individual exposure" (EPA91a). In both cases, EPA describes the RME concept as an approach which uses standardized exposure pathways and default exposure factor values to calculate maximum reasonable estimates of contaminant intake and risk for individuals in an exposed population.

The RME approach provides estimates of individual intake and risk that are protective and reasonable, but not the worst possible case. EPA developed the RME concept and standardized exposure scenarios and assumptions to: (1) reduce unwarranted variability in assumptions used in baseline risk assessments to characterize potentially exposed populations, and (2) achieve consistency in evaluating site risks and setting cleanup goals at CERCLA sites.

The Agency recognizes that exposure conditions at specific sites can and often do differ from the generic case described above. For this reason, in the Superfund program EPA has encouraged the use of site-specific scenarios and exposure factors to estimate intakes and risks at Superfund sites, provided these assumptions can be justified and documented (EPA89a).

Table 14-1. Comparison of EPA, DOE, and NRC Intake Rates and Exposure Assumptions

Factor Category	Parameter (Units)		Agency Default Values			Distribution of Values Reported in the List References					Comments
			EPA	DOE	NRC	Mean±SD	90th%	95th%	RME	Range	
Intake Rates	Drinking Water Ingestion Rate (l/d)	Residential	2	1.4	2	1.4±0.4	1.9		2	0.3-3	For worker exposures, EPA assumes half the residential daily intake consumed during an 8-hour work day.
		Commercial/ Industrial	1	NS*	NS						
	Inhalation Rate (m^3/d)	Residential	20	23	29	14±4			30		DOE uses ICRP reference man data: 16 hours resting. NRC also uses ICRP data but assumes 24 hours of light activity.
		Commercial/ Industrial	20	NS	NS						
	Soil Ingestion Rate (mg/d)	Child Resident	200	NS	NS	105±82				0-800	EPA assumes exposure durations of 6 years for children and 24 years adults. The weighted intake rate is 120mg/day for 30 years.
		Adult Resident	100	100	50	71±77				0-800	
		Commercial/ Industrial	50	NS	NS					0.5-480	
	Leafy Vegetables (g/d)	Total	NS	38	30	40±15	75	95	175	3-200	EPA does not distinguish "leafy vegetables" from all vegetables.
		Contaminated Fraction	NS	0.5	0.25	0.25			0.4		
		Actual Intake (total x fract.)	NS	19	7.5	10			70		
	Non-Leafy Vegetables (g/d)	Total	200	236	140	200±83	314	422	770	26-510	DOE values assume that non-leafy vegetables are 54% of total intake of fruits, vegetables, and grains.
		Contaminated Fraction	0.4	0.4	0.25	0.25			0.4		
		Actual Intake (total x fract.)	80	118	35	50			308		
	Fruits (g/d)	Total	140	96	126	140±58	268	327	313	30-487	DOE values assume that fruits are 22% of total intake of fruits, vegetables, and grains.
		Contaminated Fraction	0.3	0.5	0.25	0.2			0.3		
		Actual Intake (total x fract.)	42	48	32	28			94		

Table 14-1. Comparison of EPA, DOE, and NRC Intake Rates and Exposure Assumptions (Continued)

Factor Category	Parameter (Units)		Agency Default Values			Distribution of Values Reported in the List References					Comments
			EPA	DOE	NRC	Mean±SD	90th%	95th%	RME	Range	
Intake Rates	Grains (g/d)	Total	NS	105	189	125					EPA does not use grains in risk calculations (0% of homegrown grains are consumed). DOE values are calculated assuming grains are 24% of total intake of fruits, vegetables and grains.
		Contaminated Fraction	0	0.5	0.25						
		Contaminated Intake	NS	53	47						
	Milk (ld)	Total	0.4	0.25	0.27	0.4±0.01			0.85	0.25-1.0	DOE assumes 100% of the milk is contaminated for areas greater than 20,000m^2, and applies a correction factor for smaller areas. NRC lists 0.31/day as an average daily intake.
		Contaminated Fraction	0.4	1	NS	0.4	0.75				
		Contaminated Intake	0.16	0.25	NS	0.16			0.3		
	Beef and Poultry (g/d)	Total	170	173	214	100±2			300	67-124	DOE assumes 100% of the meat is contaminated for areas greater than 20,000m^2, and applies a correction factor for smaller areas. EPA numbers are for beef only: data was available for poultry and eggs. NRC lists 260 g/day as an average daily intake.
		Contaminated Fraction	0.44	1	NS	0.44					
		Actual Intake (total x fract.)	75	173	NS	44			75		
	Fish (g/d)	Total	54	15	27	12±12		42	58	0-140	Mean and 95th% values listed are for all consumers. A median 90th% for fishermen are 30 g/day and 140g/day. NRC assumes 19 g/day as an average daily intake.
		Contaminated Fraction	1	0.5	NS						
		Actual Intake (total x fract.)	54	7.5	NS				54		
	Other Seafood (g/d)	Total	NS	2.5	NS	2.1±2.0			14		EPA and NRC do not specify separate values for "other seafood." NRC assumes 2.7g/day as an average daily intake.
		Contaminated Fraction	NS	0.5	NS						
		Actual Intake (total x fract.)	NS	1.2	NS						

Table 14-1. Comparison of EPA, DOE, and NRC Intake Rates and Exposure Assumptions (Continued)

Factor Category	Parameter (Units)		Agency Default Values			Distribution of Values Reported in the List References					Comments
			EPA	DOE	NRC	Mean±SD	90th%	95th%	RME	Range	
Exposure Assumptions	Exposure Time (h/d)	Indoors-Residential	NS	12.5	13	14.2±2.5	24			2-24	
		Indoors-Commercial/ Industrial	NS	NS	NS	7.5±6.9	11.2			0-16	Calculated from EPA89 assuming 8 hours as an average work day.
		Outdoors-Residential	NS	6.3	4.7	0.72±0.89	2.4			0-24	
		Outdoors-Commercial/ Industrial	NS	NS	NS	0.5±0.6	1.8			0-7.7	Calculated from EPA89 assuming 8 hours as an average work day.
	Exposure Frequency (d/y)	Residential	350	350	365					0-365	EPA assumes 2 weeks vacation per year away from home.
		Commercial/ Industrial	250	NS	NS					0-365	EPA assumes 5 d/wk, 50wk/yr.
	Exposure Duration (y)	Residential	30	30	NS	9±9	30			0->33	
		Commercial/ Industrial	25	NS	NS		25				
Other Factors	Gamma Shielding Factor		0.8	0.7	0.33					0-1	
	Soil Concentration in Air (μg/m^3)		0.2	200	100	113±95			200	9-1800	
	Ratio of Indoor Dust to Outdoor Dust		NS	0.4	0.5					0-1	
	Dilution Factor for Drinking Water		1-100	C*	C					1-100	EPA assumes dilution factors of 1, 10, and 100.
	Livestock Soil Intake Rate (kg/d)		NS	0.5	0.6	0.6±0.7				0.2-2.9	
	Fodder Intake Rate for Beef (kg/d)		NS	68	44						DOE based on IAEA92, NRC based IAEA82.
	Fodder Intake Rate for Milk (kg/d)		NS	55	67						DOE based on NCRP91, NRC based on IAEA82.

Table 14-1. Comparison of EPA, DOE, and NRC Intake Rates and Exposure Assumptions (Continued)

Factor Category	Parameter (Units)		Agency Default Values			Distribution of Values Reported in the List References					Comments
			EPA	DOE	NRC	Mean±SD	90th%	95th%	RME	Range	
Other Factors	Volatilization Factor for Rn-222 (pCi/m^3 per pCi/g)	Indoors	NS	C*	NS	1250±3110	3400	5000	4000	400	Data from EPA's National Residential Radon Survey assuming 1pCi/g Ra-226.
		Outdoors	120	C	NS	120±110				30,000 20-500	
	Volatilization Factor for Rn-220 (pCi/m^3 per pCi/g)	Indoors	NS	C	NS						Assumes 1pCi/g Ra-224 in soil.
		Outdoors	5	C	NS	100±96				25-500	

* NS = Not Specified by Agency; NC = Not considered in soil model calculations; C = Calculated by RESRAD.

EPA References:	EPA89	Exposure Factors Handbook, Office of Health and Environmental Assessment, EPA 600/8-89 043, 1989.
	EPA91	Risk Assessment Guidance for Superfund, Volume 1: Human Health Evaluation Manual, Supplemental Guidance, "Standard Default Exposure Factors", OSWER Directive 9285.6-03, 1991.
DOE References:	DOE92	Data Collection Handbook for Establishing Residual Radioactive Material Guidelines with RESRAD, 1992.
NRC References:	NRC92	Residual Radioactive Contamination from Decommissioning, NEUREG/CR-5512, PNL-7994, 1992.
	NRC77	Calculation of Annual Doses to Man from Routine Releases of Reactor Effluents for the Purpose of Evaluating Compliance with 10 CFR 50, Appendix 2, Reg Guide 1.109, 1977.
Other References:	IAEA82	Generic Models and Parameters for Assessing the Environmental Transfer of Radionuclides from Routine Releases; Exposure of Critical Groups, Safety Series No. 57, 1982.
	IAEA92	Handbook of Parameter Values for the Prediction of Radionuclide Transfer in Temperate Environments, 9th Draft, 1992.
	NCRP91	Screening Models for Releases of Radionuclides to Air, Surface Water, and Ground Water, draft document, 1991.

Residential Exposure Scenario. The Superfund guidelines employ residential exposure scenarios whenever there are homes on or near a contaminated site, or whenever future residential development is a reasonable expectation based on consideration of local zoning laws, land-use trends, and site suitability. Five exposure pathways are evaluated routinely under these scenarios to assess risks from radionuclides in soil (EPA91a): 1) direct external radiation from photon-emitting radionuclides in the soil, 2) inhalation of resuspended contaminated dust, 3) inhalation of radon and radon decay products (only when radium is present in soil), 4) ingestion of contaminated drinking water, and 5) ingestion of contaminated soil. Two additional pathways–consumption of contaminated home-grown produce and fish are also considered at some residential sites, but only when site-specific circumstances warrant inclusion.

Commercial/Industrial Exposure Scenario. The Superfund guidelines utilize occupational exposure scenarios whenever the land use is, or is expected to be, commercial or industrial. These scenarios typically assess adult worker exposures that assume exposure occurs at the workplace during an 8-hour work day, five days per week, 50 weeks per year, for 25 years. Exposure pathways considered under these scenarios are identical to those evaluated for residential exposures, with the omission of pathways for consumption of home-grown produce and fish. Values for exposure factors and intake rates assumed for commercial/industrial exposures are generally less than those assumed for residential exposures.

Agricultural Exposure Scenario. The Superfund guidelines utilize agricultural exposure scenarios whenever individuals live or work in contaminated areas zoned for farming activities, such as growing crops or raising livestock. Under these scenarios, EPA assumes farm family members are exposed through the same five principal pathways evaluated for individuals under the residential setting, plus the mandatory inclusion of the plant pathway (i.e., consumption of home-grown produce). EPA also considers additional pathways for the ingestion of contaminated beef and dairy products, but only when such pathways are valid for the site conditions and lifestyles of the onsite populations.

Additional soil exposure pathways considered under the agricultural exposure scenario include: 1) ingestion of home-grown produce (fruits and vegetables) contaminated with radionuclides taken up from soil, 2) ingestion of meat (beef) containing radionuclides taken up by cows grazing on contaminated plants (fodder), and 3) ingestion of milk containing radionuclides taken up by cows grazing on contaminated plants (fodder).

Recreational Exposure Scenario. Under the recreational exposure scenario, the Superfund guidelines include pathways for consumption of locally caught fish – both for subsistence and recreation – and for dermal exposures that might occur during swimming and wading. Fish pathways are evaluated only when there is access to a contaminated water body large enough to produce a consistent supply of edible-sized fish over the anticipated exposure period. Pathways for assessing exposures during swimming and wading are currently being re-evaluated by EPA, along with other potential recreational exposure pathways, such as hunting and dirt-biking.

14.3.5 Exposure Scenarios Considered by DOE and the NRC

In general, the Department of Energy and the Nuclear Regulatory Commission consider similar land-use scenarios in the remediation of actual sites (DOE93 and NRC92). However, in some cases, DOE or NRC may evaluate additional exposure scenarios and pathways that are not based on any specific land-use consideration – such as the intruder exposure scenario – or may apply different default values for exposure factors and intake rates than those currently recommended by EPA. Table 14-1 compares EPA, DOE, and NRC default exposure factor values. It should be noted that all three agencies strongly recommend the use of site-specific data for modeling doses and risks, but only when the data are available and meet appropriate data quality objectives and data usability requirements.

14.4 SCOPE OF COMPLIANCE ASSESSMENTS (§194.54)

In accordance with §191.15(a) and §191.24(b), calculations of compliance with the individual and ground-water protection requirements must consider the undisturbed performance of the disposal system. "Undisturbed performance" is defined at §191.12(p) as "the predicted behavior of a disposal system, including consideration of the uncertainties in predicted behavior, if the disposal system is not disrupted by human-intrusion or the occurrence of unlikely natural events."

To clarify the Agency's intent for this requirement, §194.54 specifies that any application for certification of compliance shall include information which:

(1) identifies the potential processes, events, or sequences of processes and events that may occur over the regulatory time frame;

(2) identifies the processes, events, or sequences of processes and events that may be included in compliance assessment results provided in any compliance application; and

(3) documents why any processes, events or sequences of processes and events identified under paragraph (a)(1) of this section were not included in compliance assessment results provided in any compliance application.

Unlike the containment requirements, the individual and groundwater protection requirements do not apply to cumulative releases nor do they contain probabilistic requirements, such as the requirement that certain releases be less than 1 in 1,000 likely to be exceeded (191.13). Instead, the individual and groundwater requirements apply to the doses received during one individual's lifetime, versus 10,000 years for the containment requirements. Further, the expected value of the dose received -- the mean value -- must be less than the applicable dose limit, for example, 15 mrem in the case of the individual protection requirements. There is no regulatory significance to the probability with which the dose limit will be exceeded, and hence these requirements cannot be treated analogously to the probabilistic containment requirements. Therefore, providing a numerical cut-off for probability, such as the 1 in 10,000 threshold test applicable to performance assessments, would not be applicable. However, some screening of processes and events was contemplated in 40 CFR part 191, which in the definition of "undisturbed performance" in 40 CFR part 191 state that compliance assessments may exclude from consideration any unlikely natural processes and events.

Several differences emerge upon examination of the performance assessments needed for the containment requirements and the compliance assessments needed for the individual and groundwater protection requirements. For example, the individual protection requirements apply only to the accumulation of dose over an individual's lifetime versus 10,000 years in the containment requirements. Second, as just explicated, the individual and groundwater protection requirements are not probabilistic, unlike the containment requirements. Third, whereas the focus of the individual and groundwater protection requirements is on the contribution of natural processes and events to doses to individuals, the containment requirements focus on the contribution such processes and events make toward releases of radionuclides to the accessible environment. In view of these considerations, the Agency recognized that the significantly different form of the containment requirements versus the individual and groundwater protection requirements necessitated a different treatment of the screening of processes and events.

In compliance assessments, therefore, the Agency requires that a qualitative judgment be made regarding the likelihood with which groundwater and individual exposure pathways will be affected, over the time scale of an individual's lifetime (not 10,000 years as in the containment requirements) by the occurrence of different natural events. Although the universe of processes and events considered in the performance assessments (for the containment requirements) will closely resemble that of compliance assessments, the different regulatory requirements attending each analysis, as noted above, might allow for subtle differences regarding whether the individual events should be included in the analysis. As with performance assessments, the final rule at §194.54(a) requires compliance applications to document why any processes and events or sequences of processes and events that may occur over the regulatory time frame were not included in compliance applications.

14.5 RESULTS OF COMPLIANCE ASSESSMENTS (§194.55)

As discussed above, the part 191 disposal standards require that compliance assessments include consideration of the uncertainties associated with the undisturbed performance of the disposal system. To accomplish this assessment, it is necessary to identify all disposal system parameters that can affect the performance of the WIPP, as well as to identify the uncertainty associated with each parameter. This approach is identical to the one used to certify and demonstrate compliance with the containment requirements of 40 CFR part 191.

As part of this approach, EPA requires a three-step process, whereby:

1. all uncertain disposal system parameters are identified;
2. probability distribution functions are developed for these parameters (a probability distribution function assigns a probability of occurrence to each value for a given parameter); and

3. following steps 1 and 2, statistical sampling techniques are used to draw random samples from across the full range of probability distributions for parameter values used in compliance assessments.

The Agency believes that this process will help ensure that all possible values of a parameter have been considered in compiling compliance assessment results.

Two types of statistical sampling techniques are used frequently, namely the Monte Carlo and Latin Hypercube techniques. The Monte Carlo technique uses a random sampling scheme, which, as the name implies, involves the selection of values for a particular parameter at random within the predefined probability function for the parameter. The major disadvantage of this technique is that a large number of iterations is necessary to ensure that the selected values are sampled adequately. In comparison, the Latin Hypercube technique uses a special case of stratified sampling that involves the systematic partitioning of the range of values for a particular parameter into some number of strata. The principal advantage of this technique is that it requires less sampling iterations to ensure that the entire range of values is represented, because it draws samples from each stratum.

Also under §194.55, EPA requires that the range of estimated radiation doses to individuals (as generated through use of the computational techniques referred to above), and the range of estimated radionuclide concentrations in ground water must be large enough such that the maximum estimate generated exceeds the 99th percentile of the population of estimates with at least a 95% probability. The "population of estimates" refers to the set of all possible estimates that can be generated from all disposal system parameter values used in compliance assessments. A single estimate, in effect, samples this population.

The Agency is including this provision for the purpose of ensuring that there is a 95% probability that 99% of all possible values have been exceeded by the maximum estimate generated. This is similar to the requirement for the number of CCDFs (complementary cumulative distribution functions) which must be generated for purposes of compliance with the containment requirements.

In order to assure that all pertinent information is provided to the Agency, EPA is also requiring that compliance applications display the full range of estimated radiation doses and the full range of estimated radionuclide concentrations. The Agency believes that this requirement will help ensure that a full range of values is considered in compliance assessments.

Finally, the Agency requires that any compliance certification application provide information which demonstrates that there is at least a 95% level of statistical confidence that the mean and the median of the full range of estimated radiation doses and of the full range of estimated radionuclide concentrations meet the requirements set forth in sections 15 and subpart C of 40 CFR part 191. The mean estimate provides a measure of compliance that expresses the average impacts of the disposal system on individuals and ground water. The median estimate provides a measure of compliance that expresses the central tendency of a population of estimates. Specifically, the median represents the point that a calculated estimate would be equally likely to fall above or below. Insofar as both statistics contain useful information, the Agency's approach assures that both meet the limits of the individual and ground-water protection requirements.

It is important to note that a reasonable expectation of compliance with the individual and ground-water protection requirements will not be based solely on a final statistical estimate of doses to individuals or radionuclide concentrations in ground water. Whether a reasonable expectation of compliance will be achieved or not will be evaluated on the basis of the full record before the Agency and a thorough consideration of the methods and assumptions that produced compliance assessment results. For instance, in certifying and determining compliance, the Agency will consider such factors as the reasonableness of the processes and events considered, the appropriateness of any expert judgment elicitation used to provide inputs to the assessments, the adequacy of peer review, the quality of the models, and the quality of data inputs to those models.

14.6 REFERENCES

DOE93 Department of Energy, "Manual for Implementing Residual Radioactive Material Guidelines Using RESRAD, Version 5.0," Final Draft, 1993.

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EPA89b Environmental Protection Agency, "Exposure Factors Handbook," EPA/600/8-89/043, 1989.

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EPA92 Environmental Protection Agency, “Guidance on Risk Assessment for Risk Managers and Risk Assessors,” Memo from F. Henry Habicht II to Assistant and Regional Administrators, February 26, 1992.

EPA94 Environmental Protection Agency, “Draft Guidance for Soil Screening Level Framework, Quick Reference Fact Sheet, Review Draft,” 1994.